Human Research Protection Program Accreditation: An NIH IRP Update

Where are we now?

What's next?

What tools are available to help prepare?

Clinical Trials Seminar Series
9-25-2013

Intramural Research Program
Our Research Changes Lives

one program
many people
infinite possibilities

AAHRPP Accreditation Update:

Objectives:

- Discuss the benefits for accrediting a Human Research Protections Program (HRPP).
- Describe the HRPP accreditation application process.
- Discuss the current and future status of the NIH's application.
- Describe the OHSRP resources available for staff.

AAHRPP Accreditation Update:

Objectives:

- Discuss the benefits for accrediting a Human Research Protections Program (HRPP).

What is the NIH HRPP?

The NIH HRPP is a program that establishes policies and procedures, responsibilities and training requirements to protect the welfare of human subjects who participate in research conducted or supported by the Intramural Research Program of the National Institutes of Health (NIH).

Which NIH officials lead the NIH HRPP?

The Institutional Official: Michael Gottesman, MD,
Deputy Director of NIH for Intramural Research (DDIR)

Steve Holland, MD,
Deputy Director for Intramural Clinical Research (DDICR)

Lynnette Nieman, MD, Director,
Office of Human Subjects Research Protections (OHSRP)

Charlotte Holden, JD, Deputy Director
Office of Human Subjects Research Protections (OHSRP)

What is AAHRPP?

The Association for the Accreditation of Human Research Protection Programs, (AAHRPP) promotes high-quality research through an accreditation process that helps organizations worldwide strengthen their human research protection programs (HRPPs).

Why is NIH pursuing accreditation?

- To undergo a comprehensive self-evaluation to ensure that NIH follows federal regulations and local policies in a uniform way
- To set policies in writing if they do not exist
- To streamline processes
- To harmonize IRB and IC processes and policies
- To identify and disseminate best practices

Accreditation process

Objectives:

- Discuss the benefits for accrediting a Human Research Protections Program (HRPP).
- Describe the HRPP accreditation application process.

AAHRPP Expectations

- Protecting the rights and welfare of research participants must be an Organization's first priority. An Organization should promote a research environment where ethical, productive investigation is valued.
- Striving to exceed the federal requirements and continually seeking new safeguards for protecting research participants while advancing scientific progress must be integrated into an Organization's mission.

AAHRPP Expectations

- Protecting research participants is the responsibility of everyone within an Organization and is not limited to the Institutional Review Board (IRB). Accreditation examines whether the policies and procedures of the Organization as a whole result in a coherent, effective system to protect research participants and that all individuals know their roles and responsibilities.

AAHRPP Accreditation Process

- Step 1 Application: July 19, 2013 (1730 pages!) 
- AAHRPP response: August 29, 2013 
- Respond to AAHRPP questions (22 pgs)-underway now
- Step 2 Application: September 2013
- Site visit Prep: October/November 2013
- Site visit: December 2013?
- Debriefing and written comments for response
- Review at AAHRPP Council in March
- Decision

AAHRPP Accreditation Process

AAHRPP defines 3 domains of responsibility:

- Domain I: The Organization
- Domain II: The IRB
- Domain III: The Researcher and Research Staff

Domain I: The Organization

- HRPP in place, has sufficient resources,

  applied to transnational research
- Organization responds to concerns of research participants
- Organization has a QA/QI program within HRPP
- Organization has financial COI policies
- Organization follows FDA regulations
- Organization works with sponsors to apply HRPP principles to all participants

Domain II: The IRB

- The IRB structure is appropriate to the type of research and follows regulations
- Scientific review and provisions for PI COI are present
- The IRB reviews non-exempt protocols to protect subjects according to regulations
- The IRB provides additional protections for vulnerable populations
- The IRB documents its determinations

Domain III: Researcher and Research Staff

- Research Staff adhere to ethical principles and standards appropriate for their discipline.
- Research Staff have the protection of the rights and welfare of research participants as a primary concern.
- Researchers and Research Staff meet requirements for conducting research with participants and comply with all applicable laws, regulations, codes, and guidance; the Organization's policies and procedures for protecting research participants; and the IRB's or EC's determinations.
- Training and oversight are appropriate

AAHRPP Accreditation Process

Objectives:

- Discuss the benefits for accrediting a Human Research Protections Program (HRPP).
- Describe the HRPP accreditation application process.
- Discuss the current and future status of the NIH's application.

AAHRPP Accreditation Process

What is next?

- NIH submits a Step 2 application & site visit is scheduled
- NIH prepares for the site visit (education and training)
- AAHRPP site visitors review the application and conduct on-site evaluation
- AAHRPP provides a Draft Site Visit Report to NIH
- NIH has the opportunity to respond in writing to AAHRPP
- The site visit team leader reviews NIH's response/writes an evaluation
- The Council on Accreditation reviews the Draft Site Visit Report, NIH's response, and the evaluation of the response
- The Council then makes a determination regarding accreditation

AAHRPP Accreditation Process

What is next?

- NIH submits a Step 2 application & site visit is scheduled.
- NIH prepares for the site visit (education and training)
  - About 60 days before visit, OHSRP will receive list of persons to be interviewed (**mandatory**)
  - Interviewees include NIH leadership, Principal Investigators, IRB chairs, members and administrators, and research staff
  - OHSRP/HRP consultants will prepare these people

AAHRPP Accreditation Process

What is next?

- NIH submits a Step 2 application & the site visit is scheduled.

  Step 2 application includes:

  - updated SOP's
  - list of active protocols
  - list of Key Personnel

From these lists AAHRPP will choose personnel to interview and will provide a list of ~100 protocols to be pulled for review during the site visit (Electronic version? Paper?)

AAHRPP Accreditation Process

What is next?

- NIH prepares for the site visit (education and training)

  Education and training

  - Required training
  - Just in time training
  - Refresher training every three (3) years
  - Training/education in SOPs
    - Unanticipated problems
    - Principal Investigator responsibilities
    - Informed consent

OHSRP OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS
Human Research Protection Program

SEARCH

Home

Human Research Protection Program

NIH Federalwide Assurance FWA#: 00005897
Expires: 2/25/2014
Go to the OHRP search page for additional information

The Human Research Protection Program promotes the rights and welfare of human subjects who participate in research conducted by the Intramural Research Program (IRP) of the NIH

About the HRPP

Office of Human Subjects Research Protections

This office sets the policy and provides regulatory oversight for the HRPP

Policies and NIH Standard Operating Procedures

Required HRPP Training

NIH IRP Investigators, Research Team Members, IRB Members and OHSRP Staff should select the link below to access the HRPP Training site

Required HRPP Training

NIH Intramural IRBs

Click the link below to contact each NIH Intramural Institutional Review Board (IRB) Office

NIH IRB Offices

Committees

IRB Professional Administrators Committee (IPAC)

Human Subjects Research Advisory Committee (HSRAC)

NIH IRB Members

NIH IRB Member Tools

NIH IRB Member Training

Investigator Resources

Information and resources for investigators and research staff conducting research in the NIH Intramural Research Program (IRP)

Guidelines for Research Involving Humans

Forms, Templates and Tools

NIH Resources

NIH Resource Links

Regulations and Ethical Guidance

Office of Human Research Protections (OHRP)

45 CFR 46- The Common Rule

The Belmont Report

Search for Federalwide Assurances

Guidance

Food and Drug Administration (FDA)

21 CFR 50-Informed Consent and Children

21 CFR 56- Institutional Review Boards

21 CFR 312-INDs

LATEST NEWS:

PLEASE NOTE: The CITI Training Site has been restored. Access CITI training from "Required HRPP Training" page

New! See "Policies and NIH Standard Operating

Contact OHSRP

Office of Human Subjects Research Protections (OHSRP)
Building 10, (The Warren G. Magnuson Clinical Center)
Room 2C146, Bethesda, MD 20892-1154

Phone: 301-402-3444
Fax: 301-402-3443

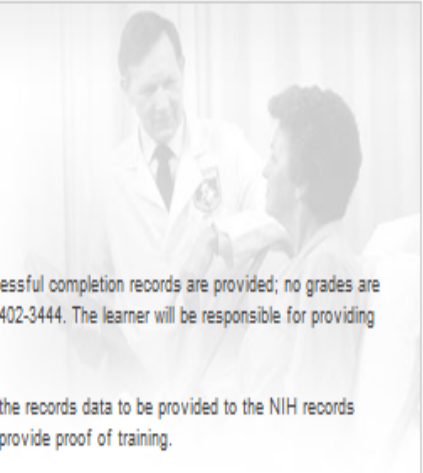
External Resources

ClinicalTrials.gov

FDA

OHRP

Welcome to the NIH HRPP Training Access Page



NIH Completion Records Database

Records are uploaded once per week. Records are provided by the training vendor. Only successful completion records are provided; no grades are provided. If a learner would like a record removed from the database, contact OHSRP at 301-402-3444. The learner will be responsible for providing proof of training.

Please note: NIAID GCP students must grant permission through the NIAID GCP website for the records data to be provided to the NIH records database. If permissions are not granted the record will not be provided and the student must provide proof of training.

Access to the "Responsible Conduct of Research" aka "NIH Research Ethics" course and case studies is provided as a courtesy; however completion records are not provided to the training database. Staff is expected to provide proof of training.

Search for Completed Training Records

Policy

The policy regarding training requirements for research staff of the NIH Intramural Research Program is addressed in HRPP SOP 25. For more information on training requirements see Policies and NIH Standard Operating Procedures

Training Cycle and Proof of Training

All new research staff must complete training before participating on a protocol submitted to an NIH IRB for review.

Refresher training is required every 3 years.

OHSRP maintains a database of completed training records that will be accessible to NIH Investigators, Clinical Directors, IRB office staff, Protocol Navigators and Human Research Protections Program (HRPP) staff. However, you should download and retain completion certificates for all courses that you complete successfully.

Instructions

Please review the types of research below and click the link below the category that is the best match for the type of research you conduct.

Types of Research

Clinical Research

Clinical research is defined as research with humans that involve interactions or interventions. This includes: studies of healthy physiology or

Department of Health and Human Services | National Institutes of Health

OHSRP OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS
Human Research Protection Program

SEARCH

Home

Home >Required HRPP Training >NIH HRPP Training Access Search Page

Welcome to the NIH HRPP Training Access Search Page

Last Name: Sanders
First Name: Margaret
IC: OD
Month:
Year (4 digits):

Search All Records

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150%

Favorites Suggested Sites OHSRP PTMS PeopleNet FDA PubMed Dictionary 45CFR46 UpToDate MedDiction FWA# OHRP NIH Library online journals CFR-Title 21
NIH HRPP Training Access Search Page
Page Safety Tools

Welcome to the NIH HRPP Training Access Search Page

Last Name	First Name	IC	Email	Course Name	Stage	Date Completed	Expiration Date
Sanders	Margaret	OD	margaret.sanders@nih.gov	Biomedical 101	Basic Course	10/28/2012	10/28/2015
Sanders	Margaret	OD	margaret.sanders@nih.gov	GCP for non PI's	Stage 1	10/29/2012	10/29/2015
Sanders	Margaret	OD	margaret.sanders@nih.gov	Vulnerable Subjects - Research Involving Children	Stage 1	10/29/2012	10/29/2013
Sanders	Margaret	OD	margaret.sanders@nih.gov	Vulnerable Subjects - Research Involving Pregnant Women Fetuses and Neonates	Stage 1	10/29/2012	10/29/2013
Sanders	Margaret	OD	margaret.sanders@nih.gov	Vulnerable Subjects - Research Involving Prisoners	Stage 1	10/29/2012	10/29/2013
Sanders	Margaret	OD	margaret.sanders@nih.gov	Vulnerable Subjects - Research Involving Workers/employees	Stage 1	10/30/2012	10/30/2013
Sanders	Margaret	OD	margaret.sanders@nih.gov	Genetic Research in Human Populations	Stage 1	10/30/2012	10/30/2015
Sanders	Margaret	OD	margaret.sanders@nih.gov	Stem Cell Research Oversight	Stage 1	10/30/2012	10/30/2013
Sanders	Margaret	OD	margaret.sanders@nih.gov	NIH CRT		10/14/2012	
Sanders	Margaret	OD	margaret.sanders@nih.gov	GCP for PI's	Basic Course	5/23/2013	5/22/2016

Instructions

Please review the types of research below and click the link below the category that is the best match for the type of research you conduct.

Types of Research

Clinical Research

Clinical research is defined as research with humans that involve interactions or interventions. This includes: studies of healthy physiology or mechanisms of disease; therapies or interventions for disease; clinical trials; or studies to develop new technologies related to disease. Studies may or may not involve FDA-regulated research. Identifiable specimen or data collections or repositories that support clinical research also are included under this category of research.

Training:

If you are a Principal Investigator, Associate Investigator, Research Contact, Study Coordinator or a person who obtains informed consent select the link below:

- Clinical Research Staff

Epidemiological and Behavioral Research

Epidemiological or Behavioral Research investigates individual or group characteristics or behavior including: collections of data from voice, video, digital, and imaging recordings; research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices or social behavior; research employing survey, interview or oral history, focus groups; or human factor evaluation. Identifiable specimen or data collections that support behavioral or epidemiological study are also included under this category of research.

Training:

If you are a Principal Investigator, Associate Investigator, Research Contact, Study Coordinator or a person who obtains informed consent select the link below:

- Epidemiological or Social Behavioral Research Staff

Basic Science Research

Basic science research is conducted to aid and support the body of medical and scientific knowledge through preclinical scientific work. This work may or may not include human specimens, derivatives or data.

Training:

Select the link below:

- Basic Science Researcher

HRPP Staff: Chairs, Members and Staff of the NIH IRBs and OHSRP Staff

Training:

Select the link below:

- HRPP Staff

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Clinical Research

Instructions

Training is based on your role or the type of research you conduct. For example, clinical research staff that conduct FDA-regulated research must take a Good Clinical Practice (GCP) course, while clinical research staff that conduct natural history studies or only obtain informed consent do not.

Review the categories below to determine which courses you are required to complete. Additionally, review the Just-in-Time and optional courses. Just-in-Time courses are quick 10-15 minute courses that can be taken before starting a protocol that involves special populations such as children or genetic or stem cell research. Your IC may have additional training requirements.

Refresher courses are required every 3 years.

Download and retain completion certificates for all courses that you complete successfully.

Required Courses

Clinical Research Staff conducting FDA-regulated Research (involving an IND, BB IND, IDE or ITP)

- Either the NIH Clinical Research Training (CRT) course without the regulatory module or CITI Biomedical module; or Ethical and Regulatory Aspects of Clinical Research offered annually by CC Bioethics.; And
- Either the NIAID GCP or the CITI GCP Training

NOTE: While both GCP courses cover the same content, the NIAID GCP course takes approximately 3 hours to complete, while the CITI GCP course takes about 4 hours to complete.

All other Clinical Research staff not conducting FDA-regulated Research and those Staff who only obtain informed consent

- NIH Clinical Research Training (CRT) course or CITI Biomedical module; or Ethical and Regulatory Aspects of Clinical Research offered annually by CC Bioethics

CITI Training Information

- There is a test-out option for the following CITI module: CITI Good Clinical Practice
- To test-out of a required course, the user must score 80% in the required content area.
- Modules take 20-30 minutes to complete.
- If the user cannot complete training, the user should complete the current module and return to the course at a later time.
- The user must achieve a score of 80% for each module quiz in order to receive a Certificate of Completion for each module.
- If you have taken CITI courses at another institution in the last 12 months and would like credit for those courses, contact the CITI helpdesk at 305-243-7970 and request that your records be merged with your NIH account. First however you must log into CITI using the link below and record your NIH Member ID. Provide this number to the CITI helpdesk.
- CITI training is transferrable to other non-NIH institutions when you leave the NIH or as may be required by other collaborating institutions.

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Education credits for a fee for more information select "CME/CEU Credits" by your completed course work on the CITI landing page.

Just-in-Time or Optional Courses

Just-in-Time CITI courses will be required if you conduct research involving these areas, but are otherwise optional. Note that the GCP courses are optional, if you do not conduct FDA-regulated research.

Just-in-Time CITI courses:

- Biomedical- Vulnerable Subjects - Research with Children
- Biomedical- Vulnerable Subjects- Research with Pregnant Women, Human Fetuses or Neonates
- Biomedical- Vulnerable Subjects- Research with Prisoners
- Biomedical- Vulnerable Subjects- Workers/Employees
- Genetic Research in Human Populations
- Stem Cell Research Oversight
- International Studies- ICH Overview and ICH- Comparison Between ICH GCP E6 and US FDA Regulations

Training Links

- Clinical Research Training Course
- NIAID GCP Training
- CITI Courses
- Ethical and Regulatory Aspects of Clinical Research offered annually by CC Bioethics

Just in time training (JIT)

JIT courses: Required if conducting research involving these subject areas (otherwise optional). IRBs or PIs may require investigators or research staff to complete these courses.

- Biomedical- Vulnerable Subjects - Research with Children
- Biomedical- Vulnerable Subjects- Research with Pregnant Women, Human Fetuses or Neonates
- Biomedical- Vulnerable Subjects- Research with Prisoners
- Biomedical- Vulnerable Subjects- Workers/Employees
- Genetic Research in Human Populations
- Stem Cell Research Oversight
- NIAID GCP course
- CITI GCP modules

Required Training for NIH Investigators

The courses can be accessed by the following steps:

Visit the Office of Human Subjects Research Protections website at http://ohsr.od.nih.gov/

1: Proceed to Human Research Protection Program (NIH login) under NIH Intramural Research Resources

2: Scroll down first column to Required HRPP Training

3: Determine type of research or role type

4: Review instructions on required/optional courses

5: Click desired training

For questions, contact Chris Brentin, OHSRP 301.402.3444

OHSRP OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS
Human Research Protection Program

SEARCH

Home

Human Research Protection Program

NIH Federalwide Assurance FWA#: 00005897
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Office of Human Subjects Research Protections

This office sets the policy and provides regulatory oversight for the HRPP

Policies and NIH Standard Operating Procedures

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NIH IRB Member Tools

NIH IRB Member Training

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21 CFR 312-INDs

LATEST NEWS:

PLEASE NOTE: The CITI Training Site has been restored. Access CITI training from "Required HRPP Training" page

New! See "Policies and NIH Standard Operating

Contact OHSRP

Office of Human Subjects Research Protections (OHSRP)
Building 10, (The Warren G. Magnuson Clinical Center)
Room 2C146, Bethesda, MD 20892-1154

Phone: 301-402-3444
Fax: 301-402-3443

External Resources

ClinicalTrials.gov

FDA

OHRP

Policy and Procedures

- New! NIH HRPP SOP Listing by Topic
- IC AAHRPP Contact List
- New! Introduction to the NIH Human Research Protection Program v1-19-2013
- New! HRPP SOP 1- HSR and the NIH IRB System v1-19-2013
- New! HRPP SOP 2 - IRB Membership and Structure v1-19-2013

New! HRPP SOP 2 Attachment - IRB Roster Template v1-19-2013

- New! HRPP SOP 2 Attachment - NIH IRB Protocol Review Standards v1 6-24-2013
- New! HRPP SOP 3 - Management and Administrative Operations of the IRB
- New! HRPP SOP 4 - Human Research Protection Program (HRPP) Documentation and Records
- New! HRPP SOP 5 - NIH Research Activities with Human Data/Specimens
- New! HRPP SOP 6 - Determinations, Including Exemptions Made by the Office of Human Subjects Research Protections (OHSRP)
- Expedited Review: IRB Reviewer Determination Form
- New! HRPP SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)
- New! HRPP SOP 7A - Requirements for Expedited Review of Research by NIH Institutional Review Boards
- New! HRPP SOP 7B - Requirements for the Conduct of Research Review at a Convened NIH Institutional Review Board (IRB) Meeting
- New! HRPP SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols
- New! HRPP SOP 9 - Continuing Review by the Convened IRB
- New! HRPP SOP 10 - Amendments to IRB-approved Research
- New! HRPP SOP 11- Suspensions and Terminations of IRB Approval and Administrative Holds
- New! HRPP SOP 11A - Closure of an IRB-approved protocol
- New! HRPP SOP 12 - Requirements for Informed Consent
- New! HRPP SOP 13 - Recruitment, Selection and Compensation of Research Subjects
- New! HRPP SOP 14A - Research Involving Vulnerable Subjects (General Considerations)
- New! HRPP SOP 14B - Research Involving Pregnant Women, Human Fetuses and Neonates
- New! HRPP SOP 14C - Research Involving Prisoners
- New! HRPP SOP 14D - Research Involving Children
- New! HRPP SOP 14E - Research Involving Adults Who Are or May Be Unable to Consent
- New! HRPP SOP 14F - Research Involving NIH Staff as Subjects
- New! HRPP SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications
- New! HRPP SOP 15A - Research Regulated by the Food and Drug Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products)
- New! HRPP SOP 15A - NIH Fillable Emergency-use IND NIH Approval Form
- New! HRPP SOP 15B - Research Regulated by the Food and Drug Administration (FDA): Information and Policies for Investigational Device Exemption (IDE) Applications
- New! HRPP SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations
- NIH Problem Report Form Fillable v2
- New! HRPP SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP)
- New! HRPP SOP 17 - Data and Safety Monitoring v3-22-2013
- New! HRPP SOP 18 - Privacy and Confidentiality
- New! HRPP SOP 19 - Investigator Responsibilities v3-22-2013
- New! HRPP SOP 20 - NIH HRPP Requirements for Collaborative Research
- New! HRPP SOP 20A - Obtaining a Reliance (Authorization) Agreement at the NIH
- New! HRPP SOP20B - NIH IRB Responsibilities When Reviewing Local Context Considerations for Offsite Research
- New! HRPP SOP20C - Responsibilities When the NIH Intramural Research Program Serves as a Coordinating Center for a Multi-site Trial
- New! HRPP SOP 20D - Collaborations Involving Non-NIH Employees Working on NIH Protocols
- New! HRPP SOP 21 - Conflict of Interest Requirements for Researchers and Research Staff
- New! HRPP SOP 22 - Research Subject Information and Services and Research-related Complaints from Research Subjects
- New! HRPP SOP 23 - Quality Management System for the NIH HRPP
- New! HRPP SOP 24 - OHSRP Reporting to the Office for Human Research Protections (OHRP) and Food and Drug Administration (FDA) Regarding Unanticipated Problems, Serious or Continuing Non-compliance or Terminations or Suspensions
- New! HRPP SOP 25 - Training Requirements for the NIH Human Research Protection Program (HRPP)
- New! HRPP SOP 26 - Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Administrative Staff and IRB Committee Activities

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NIH SOPs by Number and Content Area

Administration of the NIH HRPP	
	Introduction to the NIH Human Research Protection Program (HRPP)
1	The NIH IRB System
2	IRB Membership & Structure
3	Management & Administrative Operations of the IRB
4	HRPP Documentation and Records
26	Evaluation of NIH IRB Chairs, Vice Chairs and Members, IRB Activities and IRB Staff
27	HRPP Checklists and Review Tools
Responsibilities and Training in HRPP	
25	Training Requirements for the NIH HRPP
19	Investigator Responsibilities
Types of Research Activities and Requirements for Review	
5	Research Activities with Human Specimens and Data
6	Research Activities Exempt from IRB Review
20	NIH HRPP Requirements for Collaborative Research
20A	Obtaining a Reliance Agreement at the NIH
20B	NIH Responsibilities When Reviewing Local Context Considerations for Off-Site Research
20C	Responsibilities When the NIH Intramural Research Program Serves as a Coordinating Center for a Multi-Site Trial
20D	Collaborations Involving Non-NIH Employees Working on NIH Protocols

F. Research Regulated by the FDA

1. SOP 15 "Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications"

2. SOP 15A "Research Regulated by the Food and Drug Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products)"

   See the new "Notification Form Emergency IND (EIND) NIH Approval Form" replacing NIH Form 2707- Special Patient Exemptions. See also the new FDA IND Toolbox to request approval for the EIND from the FDA.

3. SOP 15B "Research Regulated by the Food and Drug Administration (FDA): Information and Policies for Investigational Device Exemption (IDE) Applications"

G. Reporting, Evaluation and Prevention of Adverse Events, Protocol Deviations, Non-compliance and Research-related Complaints

1. SOP 16 "Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations"

   See the new "NIH Problem Report Form" replacing SAE reporting and Protocol Violation/Deviation Reporting.

Non-NIH Investigator Training

The Principal Investigator is responsible for assuring that all investigators are qualified by education, training, and experience needed to perform their delegated roles in conduct of the study (SOP 19)

- Required training for associate investigators or Adjunct Principal Investigators who are not NIH employees or contractors is not provided by the Division of Intramural Research.
- Non-NIH investigators must self-certify in writing that they have taken training required by their institution.

Non-NIH Investigator Training

If no training is required of a non-NIH investigator by their institution. (e.g. a physician in practice), he or she must provide evidence of training.

- One possible option is a free, open-access course "Protecting Human Research Participants" offered by the NIH Office of Extramural Research, at: http://phrp.nihtraining.com/users/login.php
- NIAAD GCP online training is also free and can be accessed at https://gcplearningcenter.niaid.nih.gov/Pages/default.aspx
- Alternatively, investigators can use other publically available sources (e.g. CITI) for a fee.

Protecting Human Research Participants

NIH Office of Extramural Research

NIH Office of Extramural Research

User Login / Registration

Returning Users

Email:

Password:

Log In

Having trouble logging in?

New to PHRP Course

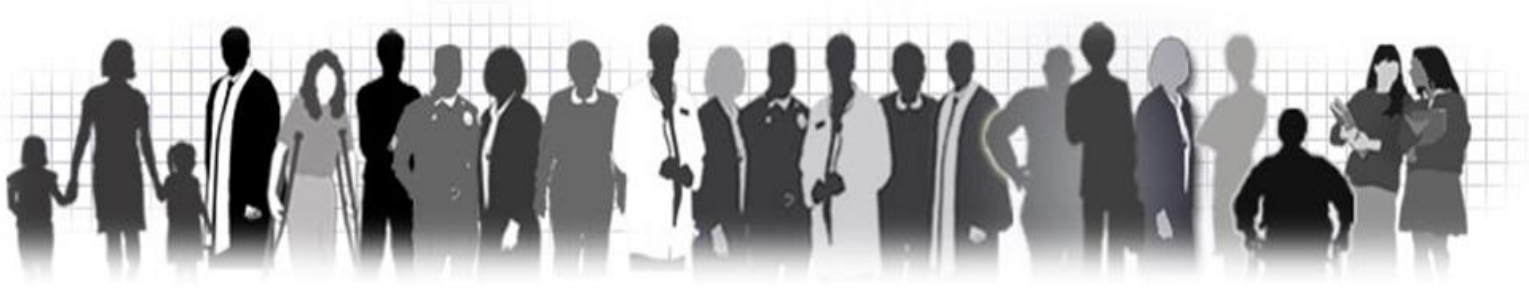
If you are entering the course for the first time, you must complete a registration form to register a new account before proceeding.

Registration

Registration is free.

¡Sí!

... A new Spanish version of this course launched on August 4, 2010. To access the Spanish version, please click on "Español" in the upper right.



National Institute of Allergy and Infectious Diseases
National Institutes of Health

NIAID GCP Learning Center

Welcome to the Good Clinical Practices (GCP) training for individuals involved in human subjects research.

This course fulfills NIAID training requirements.

GCP Training Login Accounts are Changing

This is an announcement to all GCP Learning Center users.

The NIAID GCP Learning Center training will be updated on November 2, 2013 to use the NIH Federated Identity Service. If your training is currently in progress, please try to complete and print your certificates before November 2, 2013. The training may take up to 4 hours to complete so if you have not started the training and do not think you will be able to complete the training prior to November 2 we recommend that you begin the training after the update. If you have any questions about your in progress or completed training records after November 2, 2013 please email NIAID GCP Help Desk.

Course Login Information

This site is optimized for use with Internet Explorer 6 or a later version for Windows or Safari 4 or a later version for Macintosh. Using other browsers, including Firefox, may result in login complications.

NIH users

Login ➤

- You may login with the NIH username/password combination that you use to access your NIH desktop computer or the NIH VPN.
- In the username box enter "NIH\" followed by your NIH username (example: NIH\doej). Note the use of the backslash "\" (the key above the <Enter> key on most keyboards).

Non-NIH users

Login ➤

Already have an NIH External Account?

- In the username box enter "NIHEXT\" followed by your username (example: NIHEXT\doej). Note the use of the backslash "\" (the key above the <Enter> key on most keyboards).

Need an NIH External Account?

1. Complete the request form. An auto reply e-mail will let you know your account request was submitted successfully.
2. Within 1–2 business days you will receive an a second e-mail with a username and a temporary (one-time) password. If you do not receive this e-mail, check your spam or bulk mail folder.
3. Follow the instructions in the approval message: Go to http://password.nih.gov. Select NIHEXT as the domain. Login with your username and temporary (one-time) password and create a new personal password. *Your account is not active until you complete this step.*
4. Return to http://gcplearningcenter.niaid.nih.gov and login with your NIH External Account username and password. In the username box enter "NIHEXT\" followed by your username (example: NIHEXT\doej). Note the use of the backslash "\" (the key above the <Enter> key on most keyboards).

More Information

- Visit the Frequently Asked Questions page
- Contact the NIAID GCP Help Desk

The content of these courses is reviewed regularly by a committee of NIAID subject matter experts and is current as of the most recent revision (version 2.0 / 26 Feb 2008).

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AAHRPP Accreditation Process

What is next?

- NIH submits a Step 2 application & site visit is scheduled.
- NIH prepares for the site visit (education and training)
- AAHRPP site visitors review the application and **conduct on-site evaluation.**

The Site Visit

- The site visit will last at least 5 days and will include visits at Bethesda, Baltimore and NIEHS campuses
- Interviewees include NIH leadership, Principal Investigators, IRB chairs, members and administrators, and research staff (in groups of 3-4)

The Site Visit

- AAHRPP will review the previously pulled protocols during the site
- Site visitors be permitted to enter the facilities and have access to relevant records, policies, procedures, minutes, audits, sample protocols, consent documents, and other materials

AAHRPP Accreditation Process
What is next?

- NIH submits a Step 2 application & site visit is scheduled.
- NIH prepares for the site visit (education and training)
- AAHRPP site visitors review the application and conduct on-site evaluation.
- AAHRPP provides Draft Site Visit Report to NIH

  AAHRPP provides a Draft Site Visit Report to the Organization shortly after the site visit and no later than 30 days after the completion of the site

AAHRPP Accreditation Process

What is next?

- NIH submits a Step 2 application & site visit is scheduled.
- NIH prepares for the site visit (education and training)
- AAHRPP site visitors review the application and conduct on-site evaluation.
- AAHRPP provides a Draft Site Visit Report to NIH
- NIH has the opportunity to respond in writing to AAHRPP

  Within 30 days of the Draft Report, NIH may respond in writing to AAHRPP to identify errors of fact, to describe corrective actions it has taken in response to areas of concerns identified by the site visitors, and to report any changes it has made to its HRPP since the site visit.

AAHRPP Accreditation Process
What is next?

- NIH submits a Step 2 application & site visit is scheduled.
- NIH prepares for the site visit (education and training)
- AAHRPP site visitors review the application and conduct on-site evaluation.
- AAHRPP provides a Draft Site Visit Report to NIH
- NIH has the opportunity to respond in writing to AAHRPP
- The site visit team leader reviews NIH's response/writes an evaluation
- The Council on Accreditation reviews the Draft Site Visit Report, NIH's response, and the evaluation of the response.

AAHRPP Accreditation Process

What is next?

- NIH submits a Step 2 application & site visit is scheduled.
- NIH prepares for the site visit (education and training)
- AAHRPP site visitors review the application and conduct on-site evaluation.
- AAHRPP provides a Draft Site Visit Report to NIH
- NIH has the opportunity to respond in writing to AAHRPP
- The site visit team leader reviews NIH's response/writes an evaluation.
- The Council on Accreditation reviews the Draft Site Visit Report, NIH's response, and the evaluation of the response.
- The Council then makes a determination regarding accreditation.

  Full Accreditation for *new* applicants: for three years
  Full Accreditation for *renewing* applicants: for five years

This Presentation is Not All-inclusive: We Recommend Review of These Resources

- SOP 16 - Reporting Requirements for Unanticipated Problems, Adverse Events and Protocol Deviations: http://citfm.cit.nih.gov/ohsr/nih/ohrdocs/SOP%2016-%20FINAL%20v1%206-11-13.pdf
- SOP 16A - Allegations of Non-compliance with Requirements of the NIH Human Research Protection Program (HRPP): http://citfm.cit.nih.gov/ohsr/nih/ohrdocs/SOP%2016A%20Final%20v1%206-11-2013.pdf
- The NIH Problem Report form located on the OHSRP website under "Policies and Procedures": http://citfm.cit.nih.gov/ohsr/nih/ohrdocs/NIH%20Problem%20Report%20Form%20Fillable%20%20DDIR%20v1%206-11-13%20508.pdf
- OHRP Guidance: Reviewing and Reporting Unanticipated Problems Involving Risks to Subjects or Others and Adverse Events: OHRP Guidance (2007): http://www.hhs.gov/ohrp/policy/investigators/index.html
- FDA *Guidance for Industry and Investigators- Safety Reporting Requirements for INDs and BA/BE Studies*- (December 2012): http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM227351.pdf
- Medical Administrative Series (MAS) Policy M93-1- *Research Involving Human Subjects at the Clinical Center: Structure and Process* http://internal.cc.nih.gov/policies/PDF/M93-1.pdf

Thanks!

OHSRP 301-402-3444

http://ohsr.od.nih.gov/